

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effects of music interventions on occupational performance of premature infants hospitalized in the neonatal intensive care unit

#### Protocol summary

##### Study aim

Effects of music interventions on occupational performance of premature infants

##### Design

The study is a single blinded clinical trial in which the samples are selected by convenience sampling and then divided into two groups of experimental and control based on birth weight through stratified randomization. The sample size based on similar studies and formula is 15 for each group.

##### Settings and conduct

The research will be performed in the neonatal intensive care unit of Akbarabadi Hospital affiliated to Iran University of Medical Sciences in Tehran. With written consent from the infant caregiver or ward manager, first the demographic information questionnaire and then the Test of Infant Motor Performance and Neonatal Behavioral Assessment Scale by the blind assessor to the groups it'll be done. After the interventions, the tests will be repeated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The corrected age of the premature infant should be less than 2 months and more than 36 weeks of the fetal and infants have not any accompanying problems. Exclusion criteria: instability of the infant during the intervention.

##### Intervention groups

Infants in the control group will receive routine care and in the treatment group, music interventions will be used in addition to routine care that will play through headphones and very simple non-verbal music is used with a frequency of 20-50 Hz and volume about 50 dB. 12 sessions are performed for 3 weeks and 4 times a week, and each session lasts about 20 minutes.

##### Main outcome variables

Motor performance, Behavioral performance

#### General information

##### Reason for update

##### Acronym

NICU

##### IRCT registration information

IRCT registration number: **IRCT20191109045380N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

##### Registration date

2021-06-29, 1400/04/08

##### Registrant information

##### Name

Parinaz Tofighi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3331 3617

##### Email address

tofigi.p@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of music interventions on occupational performance of premature infants hospitalized in the neonatal intensive care unit

## Public title

Effects of music interventions on occupational performance of premature infants hospitalized

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Corrected age less than 2 months and more than 36 weeks of gestation  
Satisfaction of the infant's parent  
Participating in intervention session by the approval of the ward nurse

### Exclusion criteria:

The infant does not feeding by tube  
The baby does not connect to the device for breathing  
No cerebral hemorrhage of third degree and above  
No other accompanying problems including: severe hypoglycemia, seizures, meningitis, encephalitis, asphyxia, sepsis.

## Age

From **1 day** old to **60 days** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The samples will be select by the convenience sampling and by stratified randomization in two birth weight floors are 1500 to 2000 grams and 2000 to 2500 grams using quadri-blocks. Then will divide into two experimental and control groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Assessors who are allocated to gather data.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Musical interventions are provided in addition to the routine cares.

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

## Name of ethics committee

Ethics committee of Iran University of Medical Sciences

## Street address

Faculty of Rehabilitation Iran University of Medical Sciences, Mirdamad St., Madar Sq., Shahid Shahnazari St., Madadkaran St., Farjam St., Faculty of Rehabilitation Sciences

## City

Tehran

## Province

Tehran

## Postal code

1545913487

## Approval date

2021-02-06, 1399/11/18

## Ethics committee reference number

IR.IUMS.REC.1400.094

## Health conditions studied

### 1

#### Description of health condition studied

Premature infant over 36 weeks of gestation

#### ICD-10 code

P07.39

#### ICD-10 code description

Preterm newborn, gestational age 36 completed weeks

### 2

#### Description of health condition studied

Infants weighing 2000 grams to 2500 grams

#### ICD-10 code

P07.18

#### ICD-10 code description

Other low birth weight newborn, 2000-2499 grams

### 3

#### Description of health condition studied

Babies weighing 1750 grams to 2000 grams

#### ICD-10 code

P07.17

#### ICD-10 code description

Other low birth weight newborn, 1750-1999 grams

### 4

#### Description of health condition studied

Babies weighing 1500 grams to 1750 grams

#### ICD-10 code

P07.16

#### ICD-10 code description

Other low birth weight newborn, 1500-1749 grams

## Primary outcomes

### 1

Description

Motor performance

**Timepoint**

Before the intervention, the end of the twelfth session in the third week

**Method of measurement**

Test of Infant Motor Performance

**2**

**Description**

Behavioral performance

**Timepoint**

Before the intervention, the end of the twelfth session in the third week

**Method of measurement**

Neonatal Behavioral Assessment Scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Receiving music interventions in addition to routine care interventions. Musical interventions are played through headphones, and very simple non-verbal music is used in the frequency range of 20-50 Hz and volume about 50 dB. 12 intervention sessions are performed for 3 weeks and 4 times a week, and each session lasts about 20 minutes.

**Category**

Rehabilitation

**2**

**Description**

Control group: Infants in the control group will receive routine care, including nursing, medical, and rehabilitation interventions.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Akbarabadi hospital

**Full name of responsible person**

Dr Majid Kalani

**Street address**

Bagh Ferdows Station, Molavi Crossroads, Molavi Street

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Vice-chancellor for Research

**Street address**

Fifth floor of the headquarters, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parinaz Tofighi

**Position**  
master student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Occupational Therapy

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Maddakaran St., Shah Nazari St., Mother Square,  
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## Person responsible for scientific inquiries

**Contact**

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Iran University of Medical Sciences

**Full name of responsible person**  
Dr Mitra Khalafbeigi

**Position**  
Assistant Professor

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Ph.D.

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Occupational Therapy

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## Person responsible for updating data

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Iran University of Medical Sciences

**Full name of responsible person**  
Parinaz Tofighi

**Position**  
master student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Occupational Therapy

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information.

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

The data that are related to primary outcome will be available.

### When the data will become available and for how long

Immediately after publication.

### To whom data/document is available

Researchers working in academic institutions.

### Under which criteria data/document could be used

Performing similar research

### From where data/document is obtainable

Search databases or sending Email to Dr Mitra  
Khalafbeigi: khalafbeigi.m@iums.ac.ir

### What processes are involved for a request to access data/document

Sending Email to khalafbeigi.m@iums.ac.ir

### Comments